

REMARKS/ARGUMENTS

Claims 8-19, and 20-21, 25-26 are pending. Claims 8-19 are withdrawn. Claims 22-24 have been cancelled. Claims 20-21 has been amended. Claims 25 and 26 are newly added. Support for these amended and new claims can be found at e.g., original claim 20-24, pages 16-18, and Figures 4-5. Claims 20, 21, 25 and 26 are presented for consideration.

In the present Office Action, the Examiner has rejected the previous pending claims 20-24 for various reasons as discussed below. The Examiner's position in the present Office Action has apparently changed from her position in the previous Office Actions. For example, in the Office Action dated January 13, 2004, the Examiner advised that claims 23 and 24 were allowable. During the Examiner's interview with Dr. Yunling Ren on March 23, 2004, the Examiner advised that the outstanding rejection regarding claims 20-21 would be overcome if we set an upper and lower limit of the number of the amino acid residue and further describe the enhanced activity (see e.g., the interview summary). In the Office Action dated July 1, 2004, the Examiner again advised that claims 20-21 and 23-24 were allowable if the "confusing" phrase was clarified. Accordingly, we have amended the then pending claims to obviate the "confusing phrase." But the Examiner now changes her position to reject all the pending claims in the present outstanding Office Action.

While Applicants regret that the Examiner has changed her position and still believe that claims 20-21 and 23-24 are allowable subject matter as the Examiner's previously stated, Applicants have cancelled claims 23-24, amended claims 20-21, and added new claims 25 and 26 in response to the present Office Action. Applicants therefore respectfully request that the Examiner reconsider the rejection of the present application in view of the present amendments and the following remarks.

Sequence Compliance

The Examiner stated that the sequence containing "PXSSSS" in claim 21 lacks a sequence identification number. In response, Applicants have identified this segment as SEQ ID No:11 in claim 21 and the specification. The attachment to the present Amendment provides the sequence listing of SEQ ID No:11, and its relationship to the wild-type glucanase of SEQ ID No:3. This sequence identification number is consistent with the identification number in the computer readable sequence document that we filed with the Patent Office on July 16, 2001. Hence, the defect in connection with sequence identification number has been obviated.

Claim Rejections under 35 U.S.C. § 112

Claims 20 and 21 were rejected under 35 U.S.C. § 112, second paragraph, because the Examiner deemed that it was not clear whether the phrase "absent signal peptide" applied to the matured wild type enzyme or to the claimed "isolated truncated" enzyme. In response, Applicants have made it clear in the amended claim 20 that the phrase "absent signal peptide" applies to the "isolated truncated glucanase." Hence, this defect has been obviated in the present claims.

Claims 23-24 were rejected under 35 U.S.C. § 112, second paragraph because the use of the term "substantially identical". Since claims 23 and 24 have been canceled, and none of claims 20, 21, 25 and 26 recites such a term, this rejection has become moot.

Claims 20-21 were rejected as being not in compliance with the "written description" requirement under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner stated that the claims were drawn to a genus of glucanase variants having **any** structure comprising SEQ ID No: 1 and a C-terminal extension of 1 to 19 amino acids, wherein the extension comprises of **any**

amino acids. The Examiner also stated that the specification did not provide any direction as to what kind of residues could be added to the C-terminus of SEQ ID NO:1 to impart the mutant with enhanced glucanase activity.

New claims 25 and 26 do not have this defect. Additionally, claims 20-21, 25, and 26 have been amended to further define the isolated truncated glucanase by its activity and thermal tolerance. The activity and thermal tolerance recitation is supported in the specification in Figures 4 and 5, and in pages 16-18 as they relate to TF-glucanase and PCR-TF-glucanase. Thus, Applicants believe that the amended claims 20-21 and new claims 25 and 26 meet the written description requirement. The original specification of the present application has provided detailed information as to the desired properties of the truncated glucanase, how to assay these properties, how to make the truncated glucanase by exemplifying the two species of SEQ ID No:1 and No:2 (see pages 16-18, figure 4-5, pages 4-14, etc.). By providing such description of sufficient, relevant, and identifying characteristics of the present invention, a person of skilled in the art would recognize that the inventor had possession of the present invention. See MPEP 2163.3.

Therefore, claims 20, 21, 25 and 26 have clearly met the "written description" requirement under 35 U.S.C. 112, first paragraph.

Claims 23-24 were rejected as not in compliance with the written description requirement under 35 U.S.C. 112, first paragraph, because the use of the term "substantially identical." Claims 23 and 24 are cancelled by the present Amendment. As noted above, since none of claims 20-21, and 25-26 recites this term, this rejection has become moot.

Claims 20-21 were also rejected as not being enabled under 35 U.S.C. 112, first paragraph, because the Examiner deemed that they encompassed all the variants of SEQ ID No:

1 without limitation to the C-terminal extension. This rejection is irrelevant to new claims 25-26. As to claims 20 and 21, the applicants have now further defined the isolated and truncated glucanase by its specific thermal tolerance and activity. As noted above, the specification has provided detailed information as to how to make the claimed glucanase, how to assay the relevant properties of the glucanase, what are the desired properties of the glucanase. Provided with these specific instructions, a person of ordinary skill in the art would arrive at the present invention without any difficulty. There is no need for undue experimentation, let alone "essentially infinite choices" as stated by the Examiner, for a person of ordinary skill in the art to arrive at the present invention.

The applicants would also like to draw the Examiner's attention to the two cases cited by MPEP 2164.06(b). In *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court reversed the rejection for lack of enablement under 35 U.S.C. 112, first paragraph, concluding that undue experimentation would not be required to practice the invention. The nature of monoclonal antibody technology is such that experiments first involve the entire attempt to make monoclonal hybridomas to determine which ones secrete antibody with **the desired characteristics**. The court found that the specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples, that all of the methods needed to practice the invention were well known, and that there was a high level of skill in the art at the time the application was filed. Furthermore, the applicant carried out the entire procedure for making a monoclonal antibody against HBsAg three times and each time was successful in producing at least one antibody which fell within the scope of the claims.

In *In re Bundy*, 642 F.2d 430, 434, 209 USPQ 48, 51-52 (CCPA 1981), the court ruled that appellant's disclosure was sufficient to enable one skilled in the art to use the claimed

analogs of naturally occurring prostaglandins even though the specification lacked any examples of specific dosages, because the specification taught that the novel prostaglandins had **certain pharmacological properties and possessed activity** similar to known E-type prostaglandins.

Similar to the above two cases, claims 20, 21, 25 and 26 also recite the desired properties which are described in the specification in detail. Hence, these claims are enabled by the original specification of the present application.

Moreover, as MPEP 2164.06 instructs, the quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Telecommunications Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 490 U.S. 1046 (1989).

As noted above, the present specification has provided sufficient detail as to the desired properties of the glucanase, how to make such a glucanase, and how to assay the desired properties. Even if one of ordinary skill in the art would need to do some experimentation, he or she would only engage in **routine** experimentation.

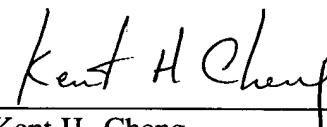
Therefore, all the pending claims 20, 21, 25, and 26 meet the "enablement" requirement under U.S.C. 112, first paragraph.

Claims 23-24 were rejected as not being enabled under 35 U.S.C. 112, first paragraph because of the use of the term "substantially identical". Claims 23 and 24 are cancelled. Again, since none of claims 20-21, 25-26 uses this term, this rejection has become moot.

Based on the forgoing, Applicants believe that the present application has been placed in condition of allowance. Applicants thereby respectfully request that the Examiner gives an early and favorable consideration of the present application.

It is believed that no other fees or charges are required at this time in connection with the present application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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